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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kimberly A. Gillis et al.	Group Art Unit: 1634
Application No.: 09/997,423	Examiner: D. B. Johannsen
Confirmation No. 6433	
Filed: November 28, 2001	
For: Expression Analysis of FKBP Nucleic Acids And Polypeptides Useful In The Diagnosis And Treatment of Prostate Cancer	
Attorney Docket No.: 102729-12 (AM100492)	

Commissioner for Patents
Washington, DC 20231

TRANSMITTAL LETTER

Dear Sir:

Enclosed are the following documents for filing in connection with the above-referenced patent application:

1. Response To Restriction Requirement; and
2. Return Receipt Postcard.

The Commissioner is hereby authorized to charge any underpayments or overpayments in connection with this filing to our Deposit Account No. 141449, Reference No. 102729-12. A duplicate copy of this sheet is enclosed.

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April 25, 2003
Date

Jasbir Sagoo, Ph.D., Reg. No. 51,177

Respectfully submitted,

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April 25, 2003 Date of Signature and Mail Deposit		By: Jasbir Sagoo, Ph.D. Reg. No: 51,177

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

In the Office Action mailed from the Patent Office on March 23, 2003, the Examiner required election of one of the following patentably distinct groups:

Group I: Claims 1-7, and 11-20;

Group II: Claims 1, 3-10 and 16;

Group III: Claims 21 and 34;

Group IV: Claims 22, 25-26, and 28;

Group V: Claims 22, 25, and 27-28;

Group VI: Claims 23-24 and 31-33; and

Group VII: Claims 29-30.

At the outset, Applicants wish to note that the invention is directed to using immunophilins, such as FK-Binding Proteins (FKBPs), *e.g.*, FKBP54, as genetic markers for the detection, diagnosis and prognosis of prostate disorders. The invention provides methods and screening assays for the detection and diagnosis of prostate cancer, as well as for testing for compounds that effect the expression levels of FKBP in prostate cancer.

Applicants respectfully traverse the restriction requirement as improper. However, for the purpose of being responsive to the outstanding Office Action, Applicants hereby elect the Group II invention (drawn to methods of assessing prostate cancer by detecting polypeptides), with traverse. Reconsideration and withdrawal of the restriction requirement is requested because the invention is drawn to measuring the expression levels of FKBPs associated with prostate cancer, especially the expression level of FKBP54. The expression level can be monitored by either measuring the nucleic acids associated with FKBPs (e.g., RNA, or DNA), or the FKBP protein levels.

As stated in the restriction requirement, "nucleic acids and polypeptides are structurally and functionally distinct molecules... the *method steps and reagents* required to *detect nucleic acids* are *separate and distinct* from those required to *detect proteins*." Thus, a more appropriate separation is based on methods for detecting nucleic acids as being patentably distinct from methods for detecting polypeptides. With this in mind, claims 1-7, 11-20 (Group I), claims 21 and 34 (Group III), as well as claims 22, 25-26 and 28 (Group IV), all of which are in class 435, subclass 6, should be grouped together as being directed to measuring *nucleic acids*. This is a more appropriate grouping because the methods and reagents required to detect the expression of FKBP nucleic acids to assess whether a subject is afflicted with prostate cancer (Group I), are the same methods and reagents required to assess the efficacy of a therapy (Group III), or to assess a potential test compound that may trigger prostate cancer (Group IV), or to identify a compound

useful for treating prostate cancer (Group IV). Despite the fact that there are different objectives, i.e., some claims involve incubating the sample with test compounds and observing the effects of such compounds on FKBP nucleic acid expression levels (claims 22 and 25), the ultimate methods and reagents for detecting the effects of such compounds remains the same. That is to say that, irrelevant of whether the expression levels of nucleic acids associated with FKBP are measured in the presence or absence of a test compound, the expression levels will nevertheless, still be measured using the same reagents to detect the nucleic acids (e.g., reverse transcriptase-PCR). Furthermore, it is conceded in the Office Action that Groups I, III, and IV belong to the same class/subclass of 435/6. Thus, searching for Group I invention will inherently also involve searching for Group III and IV inventions. Accordingly, a single search would suffice for claims 1-7, 11-20 (Group I), 21 and 34, (Group III), and 22, 25-26, and 28 (Group IV).

Furthermore, claims 23-24 and 31-33 (Group VI) are directed to antisense methods for treating cancer, which again involve measuring *nucleic acids*, and as such should be grouped with all claims directed to detecting nucleic acids.

Claims that are directed to measuring protein levels include claims 1, 3-10 and 16 (Group II), claims 21 and 34 (Group III), and claims 22, 25, and 27-28 (Group V), all of which are in class 435, subclass 7.1. As such, these claims should be grouped together as directed to detecting *polypeptides* that require the same reagents. Again, a more appropriate grouping is one that uses the same reagents to detect the expression of the FKBP polypeptide (e.g., antibodies) to assess whether a subject is afflicted with prostate cancer (Group II), as well as to assess the efficacy of therapy (Group III), potential test compounds that may trigger prostate cancer (Group V), or to identify compounds useful for treating prostate cancer (Group V). As before, even though there are different objectives, the reagents and methods used to measure FKBP polypeptide levels will nevertheless remain the same. It is conceded in the Office Action that Groups II, III, and V belong to the same class/subclass of 435/7.1. Thus, searching for Group II inventions will inherently also involve searching for Group III, and V inventions. Accordingly, a single search would suffice for claims 1, 3-10, (Group I), 21, 34, (Group III), and 22, 25, and 27-28 (Group V).

Furthermore, claims 29-30 (Group VII) are also directed to detected the effects of compounds on prostate cancer by measuring *protein activity*, and as such should be grouped with all claims directed to detecting polypeptides.

The Examiner is urged to call the undersigned at the telephone number indicated below so that any remaining issues can be discussed.

Respectfully submitted,
NUTTER, McCLENNEN & FISH, LLP

Date: April 25, 2003

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